

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

8

Applicant's or agent's file reference P 14 965 PC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CH00/00334	International filing date (<i>day/month/year</i>) 20 June 2000 (20.06.00)	Priority date (<i>day/month/year</i>) 25 June 1999 (25.06.99)
International Patent Classification (IPC) or national classification and IPC A61N 5/10		
Applicant PAUL SCHERRER INSTITUT		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 10 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 03 January 2001 (03.01.01)	Date of completion of this report 25 September 2001 (25.09.2001)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/CH00/00334

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages _____ 1,3-12 _____, as originally filed
pages _____, filed with the demand
pages _____ 2.2a _____, filed with the letter of _____ 09 July 2001 (09.07.2001)
- ☒ the claims:
pages _____ 1,2,3(in part),10(in part)11-14 _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____ 3(in part),4-9,10(in part) _____, filed with the letter of _____ 06 April 2001 (06.04.2001)
- ☒ the drawings:
pages _____ 1/4-4/4 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/CH00/00334

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 11-14

because:

- ☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 11-14

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/CH00/00334

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☒ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☐ the parts relating to claims Nos. _____

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box IV

1. The international search report was established in respect of Claims 1-10. These claims relate to two inventions which are not linked by a common inventive concept.

The application fails to meet the requirement of unity of invention (PCT Rule 13) for the following reasons:

- 1.1 Two separate inventions are described.

Invention I (Claims 1-8):

Apparatus for treating a patient by proton therapy, wherein the patient table remains accessible from one side at all times.

Invention II (Claims 9 and 10):

Apparatus for treating a patient by proton therapy, wherein a cover housing that forms the beam delivery nozzle is coupled to the patient table for conjoint movement therewith.

2. Inventions I and II have no common special technical features within the meaning of PCT Rule 13.2, and hence there is no technical relationship between the two inventions.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims	9, 10	YES
	Claims	1-8	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

D1: EP-A-0 911 064 (MITSUBISHI ELECTRIC CORP), 28 April 1999

D2: EP-A-0 864 337 (SHENZHEN OUR INTERNATIONAL TEC),
16 September 1998

1. The subject matter of Claim 1 is not inventive and therefore fails to meet the requirement of PCT Article 33(3).

Document D1, which is considered to be the closest prior art, discloses the following:

apparatus for treating a patient by proton therapy (**Figure 9**), comprising a proton beam guide that uses magnets, quadrupoles and an end-mounted proton beam guiding and controlling device (10) with a beam delivery nozzle (**Figure 9**) for guiding and directing the proton beam (31) onto the treatment field on the body of the patient; also comprising a controllably movable patient table ((27), column 13, line 22) for moving the patient into the desired position relative to the proton beam; characterised in that the proton beam guiding and controlling device (10) is mounted for rotation about a horizontal axis (the proton beam guiding and controlling device is rotatable about the axis (29); see **Figure 9**), such that the patient table,

which is positioned substantially in the plane of the axis of rotation, remains accessible from one side at all times (the table is constantly accessible from the side opposite the proton beam guiding and controlling device and from the head end).

Claim 1 differs in that the patient table is mounted for rotation in a horizontal plane about an axis running through the isocentre.

The apparatus is designed to offer an additional degree of freedom in the irradiation geometry.

However, precisely this kind of rotation of a patient table in a horizontal plane about an axis running through the isocentre in apparatus for treating a patient by proton therapy is disclosed in document D2 (Figure 16, column 2, line 45). The irradiation geometry shown in Figure 16 of D2 is equivalent to that described in the present application, and moreover the concept according to D2 of rotating a patient table about an axis running through the isocentre can also be applied to apparatus as per either the present application or D1 with proton beam guiding and controlling devices designed for rotation about the patient table (column 5, lines 10-12).

This additional degree of adjustability for the table as per D2 must be regarded as independent of the rest of the beam source and table arrangement. Clearly, although the beam source is positioned on only one side of the table, the said degree of adjustability allows irradiation of the patient from all sides. For a person skilled in the art it is immediately evident that this additional degree of freedom in the apparatus shown in **Figure 9** of D1 would offer the same advantages, and he would therefore be able to incorporate equivalent rotational freedom without making an inventive contribution. Hence the subject matter of Claim 1 does not involve an inventive step in the light of

the obvious combination of the teachings of D1 and D2.

2. Dependent Claims 2-8 do not contain any features that meet the PCT requirements relating to inventive step when taken in conjunction with the features of any of the claims to which they refer back. As demonstrated below, the additional features defined in these claims are known from the prior art, and in view of their known technical effects a person skilled in the art would be able to adopt them without hesitation.
- 2.1 The proton beam guiding and controlling devices known from the prior art (for example, D1) are rotatable through a full 360°. They are thus rotatable through angles that fall within the ranges specified in Claims 2 and 3, which in any case cannot be construed as limiting.
- 2.2 The additional feature defined in Claim 4 is known from D2 (see Figure 16). Even with the geometry according to D1, which is in fact suggested by D2 (column 5, lines 10-13), the table would be rotatable in the part of the horizontal plane which is not occupied by the proton beam guiding and controlling device.
- 2.3 The degrees of adjustability for the patient table specified in Claims 5-7 are conventional degrees of adjustability provided by all irradiation devices with isocentric geometry.
- 2.4 The additional feature involving an upstream range shifter as defined in Claim 8 is also known from D1 (Figure 9, reference sign (5)). D1 also proposes arranging the additional range shifter so that it is separate from the proton beam guiding and controlling device. Thus the placing of this device in an upstream position is merely one of two possibilities which a person skilled in the art would be able to choose according to the circumstances without contributing an inventive step.

3. According to the assumed interpretation of Claim 9 (see Box VIII below), the subject matter of the claim differs from known types of proton therapy apparatus in that the housing for the beam delivery nozzle (or the cover housing that forms the beam delivery nozzle) is not rigidly connected to the proton beam guiding and controlling device, and in that further control means are provided for coupling the movement of the patient table to that of the nozzle housing or nozzle-forming cover housing.

The nozzle housing or nozzle-forming cover housing is thus able to synchronously replicate discrete movements of the table during treatment, and hence there is no relative movement between the table and the proton beam guide housing, which movement can be perceived as disconcerting by the patient.

Such an arrangement is neither known from nor suggested by the prior art. Therefore the subject matter of Claim 9, to the extent that it can be understood (see Box VIII below), meets the requirements of PCT Article 33(2)-(4).

- 3.1 For reasons of clarity, the additional feature defined in Claim 10 has been dealt with in conjunction with Claim 9 (see Box VIII below).

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 9 fails to meet the requirements of PCT Article 6 because the subject matter for which protection is sought is not clearly defined. The said claim seeks to define its subject matter in terms of the result which is to be achieved, and in doing so merely states the problem addressed ("such that discrete movements of the patient table are synchronously replicated during treatment of a patient"). To eliminate this deficiency, the following technical features, which are needed in order to achieve this result, should have been included in the claim:

- (i) the beam delivery nozzle housing is not rigidly connected to the proton beam guide (see page 11, lines 18-20);
- (ii) the further control means (as defined in Claim 10)

The comments under point 3 in Box V assume that both these features are included in Claim 9.